IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID ZINK, et al.,	)	
Plaintiffs,	)	
	)	
v.	)	**No. 2:12-CV-4209**
	)	
GEORGE A. LOMBARDI, et al.,	)	
Defendants.	)	

REPLY IN SUPPORT OF MOTION TO AMEND SCHEDULING ORDER

Defendants insist that their new protocol reflects only "minor" changes that were themselves "suggested" by Plaintiffs and their expert, Dr. Heath, and that Plaintiffs already understand the changes and the reasons for adopting them. The evidence proves otherwise. Dr. Heath never urged that Defendants should divide propofol into an initial "clinical" dose and a larger lethal one. Since the beginning of this litigation, Plaintiffs have made clear that the Department of Corrections should abandon propofol altogether, as documented by Defendants' former expert, who testified that even clinical doses of the drug will make patients "scream at the top of their lungs as they are falling asleep." ECF Doc. 1, Ex. A (Petition ¶ 147 & Ex. 4). Neither have Plaintiffs suggested that M3 should reduce the risk of propofol-evoked pain by cutting a central line access for each and every execution, that he should administer midazolam at an unknown time and in an unknown amount, or that Defendants should conduct a "consciousness check" by assigning that task to unqualified personnel. Ex. 2 ¶¶ 15-26; Ex. 8 at 33-34, 37-41.

Those steps are solely the Defendants'. What is more, they announced them after the close of discovery, then quickly urged on summary judgment that all is definitively well as a matter of law. Plaintiffs seek modest relief: a reasonable amount of time to investigate, develop, and prove new claims concerning a new and misguided protocol.

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I. Defendants' new protocol emerged from the Defendants themselves, it does not cure the hazards described by Dr. Heath or Defendants' own expert from previous litigation, and it creates new hazards that Plaintiffs have a right to plead and develop through discovery.

It is a cruel hoax to attempt to pin Defendants' post-overtime changes of signal on Plaintiffs or their expert.[1] *See* Opposition at 1-5, 13. Dr. Heath cannot and does not recommend execution methods. Unlike M3, Dr. Heath abides by the ethical constraints of his profession, which forbid the "rendering of technical advice regarding executions" as well as "consulting with or supervising lethal injection personnel." *See* Defendants' "Reply in Support of Motion for Protective Order Regarding the Identity of Members of Missouri's Execution Team," (ECF Doc. 99), Ex. 1 at 3 (policy of American Medical Association).

Defendants misread the record in any event. Nothing in Dr. Heath's deposition remotely "suggests" that Defendants adopt the substance of their August 1 protocol. For example, it was **defense counsel** who asked Dr. Heath about modifying the protocol to begin with a "clinical" dose of propofol. *See* Ex. 8 (Heath deposition, attached) at 33. Far from endorsing that modification, Dr. Heath explained that clinical techniques cannot reliably eliminate the risk of significant or extreme pain from propofol. *Id.* at 33-34, 39. If Dr. Heath has "suggested" anything, it is that Defendants abandon the use of propofol altogether. *See* Ex. 2 ¶ 6 (protocol's "principal defect" is propofol).

Neither did Dr. Heath "suggest" that the Department administer midazolam,

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[1]Defendants assert as the opening sentence of their response that Plaintiffs filed this suit "to prevent the execution of their death sentences." Opposition at 1. Plaintiffs have litigated this case as expeditiously as possible to avoid undue delay. It is Defendants who have repeatedly prolonged the process, most recently by the eleventh-hour changes to the protocol.

whether as opaquely described in Dave Dormire's affidavit or otherwise. Again, it was defense counsel who asked about reducing the risk of propofol-evoked pain in clinical settings. Ex. 8 at 34. Dr. Heath explained that clinicians employ a two-pronged approach by giving **both** a powerful painkiller such as fentanyl and a sedative such as midazolam (which is not a painkiller). *Id.* at 37-38, 41, 43. The "great majority" of patients who undergo propofol anesthesia receive both of these drugs; but even then, there remains the "real chance" that propofol will cause pain significant or extreme pain. *Id.* at 37, 39, 41. Using these two drugs in an attempt to staunch the Defendant's self-inflicted wound from choosing propofol is therefore insufficient to meet Dr. Heath's testimony to its unfitness. *Id.* at 39.

In any event, the new protocol and its accompanying affidavit do not adopt the prevailing two-drug clinical practice. The new method includes midazolam, which serves the clinical purpose of sedating and relaxing the patient in order to reduce anxiety, and prevents the patient from remembering the experience of propofol-evoked pain after he or she awakens from surgery. *See* <<http://www.mayoclinic.com/health/drug-information/DR602763>> (last visited Sept. 8, 2013). But the new protocol does not include fentanyl or any similarly strong painkiller. "By failing to take measures to prevent propofol-evoked pain that are routinely taken in clinical practice, the MDOC needlessly exposes prisoners to increased incidence and intensity of propofol-evoked pain." Ex. 2 ¶ 7.

Neither does the new "consciousness check" come from Plaintiffs. Defendants rely on the proposition that the "consciousness check" their latest protocol is supposed to incorporate will employ "clinical methods," without saying which of their "medical personnel" (neither of whom need even be a doctor) will perform this

check, or why this Court should believe the methods they say they will use are in fact "standard clinical" methods or sufficient in the context of the defendants' plans for an execution. Opposition at 4. Dr. Heath explained that a clinically appropriate consciousness check after an initial dose of propofol is **necessary** in order to reduce the pain from a larger and lethal dose later. Ex. 8 at 39-40. As previously noted, even this step will not reliably prevent pain. *Id.* at 33-34, 39. And a consciousness check itself requires specific safeguards: "a person at the bedside in immediate proximity to the prisoner within arm's length of the prisoner [and] a person who is trained and competent and proficient to clinically assess whether the prisoner is in fact anesthetized after the administration of that initial dose of propofol." *Id.*

The new protocol provides no such thing. It states that "medical personnel" will assess the prisoner's consciousness, but without requiring that task to be performed by "board-certified" anesthesiologist M3 rather than licensed practical nurse M2. *See* Ex. 4 ¶¶ E4-E5. That material defect undermines the consciousness check's efficacy. Ex. 8 at 40. "Assessing consciousness in a patient who has received an intended anesthetic induction is a sophisticated process that is a mixture of skill, art, experience, and judgment," Dr. Heath explains. Ex. 2 ¶ 22. "In the United States the assessment of anesthetic depth after the induction of general anesthesia is undertaken only by individuals with years of training and experience." *Id.*

Needless to say, it is not Plaintiffs' fault that Defendants' new protocol creates new problems. It is the common experience of humankind that measures intended to solve one problem create other problems, even if the changes are well-intentioned. Here, the initial "clinical" dose of propofol "will directly cause some prisoners to experience their final moments of consciousness in severe pain." *Id.* ¶ 8. Central line

access will allow for the use of a larger blood vessel that may reduce the risk of propofol-evoked pain, but not without the inherently invasive and painful process of carving the central line in the first place, which has known side-effects beyond the obvious ones. Ex. 2 ¶ 18; Ex. 8 at 25-27. And midazolam may indeed make the prisoner mentally incompetent depending on the drug's quantity and timing. Ex. 2 ¶ 26; Ex. 8 at 38.

Defendants do not even try to justify the time at which they disclosed the changes in their execution method. Defendants have known since this suit began, in June 2012, that Dr. Heath attributed a risk of severe pain to the large dose of propofol announced in the May 2012 protocol. See ECF Doc. 1, Ex. A, Ex. 1 (Heath Affidavit) ¶¶ 25-36. The Court mentioned this same risk among its reasons for denying the motion to dismiss (in November 2012) and the motion for judgment on the pleadings (in March 2013). ECF Doc. 31 at 6; ECF Doc. 61 at 5. By the time of Dr. Heath's deposition on June 1, Defendants knew they might divide the propofol into a clinical dosage and a fatal one: defense counsel specifically asked Dr. Heath about this proposal. Ex. 8 at 33. That same month (if not earlier), the Department's quarterly execution rehearsal included a consciousness check after the initial propofol syringe. Ex. 9 (confidential portions of Dormire deposition) at 51-52. Yet in July, defense counsel told Mr. Dormire not to disclose prospective changes in the protocol. Ex. 1 at 28.

In short, the Defendants have made substantial changes to their protocol, and Plaintiffs had no reasonable notice of those changes until the eve of summary judgment. The Court should afford Plaintiffs a reasonable opportunity to investigate and develop their claims, and then to prove them on a feasible trial date.

II. Plaintiffs have satisfied the standard for leave to amend a complaint.

Defendants offer scattershot arguments that Plaintiffs' proposed new claims are futile. The Court should grant leave to amend freely "when justice so requires." Fed. R. Civ. P. 15(a). While leave may be denied if the amendment would be futile, the question of whether a proposed amendment is futile depends on whether it could survive a motion to dismiss under Rule 12(b)(6). *In re Senior Cottages of America*, 482 F.3d 997, 1001 (8th Cir. 2007). The Court must therefore accept Plaintiffs' factual assertions as it would those in a complaint. *Id.* The new claims satisfy the modest standard for amending.

A. Defendants, who wish to administer propofol to prisoners for a medical purpose, are subject to Missouri law governing medical anesthesia for prisoners.

Plaintiffs object to Defendants' particular choice of general anesthesia: propofol, which is widely known to cause severe pain on injection. The fact that propofol-evoked pain cannot be reliably prevented "is unquestioned within the discipline of anesthesiology." Ex. 2 (Heath declaration) ¶ 6. That is why Plaintiffs invoke Mo. Rev. Stat. § 217.420, which forbids any prisoner from being dosed with a general anesthetic without the prisoner's consent. Defendants cannot seriously argue that the Plaintiffs lack an injury in fact. Opposition at 7-8. Defendant's own former expert, Dr. Mark Dershwitz, testified that "propofol causes pain in two-thirds to three-quarters of patients, and that a subset of patients 'literally scream at the top of their lungs as they are falling asleep' because 'propofol burns.'" Order denying motion to dismiss (ECF Doc. 31) at 4. Dr. Heath agrees. He asserts "with the highest degree of medical certainty that if the current protocol is used by the MDOC, it will directly cause some prisoners to experience their final moments of consciousness in

severe pain." Ex. 2 ¶ 8.

Equally unavailing is Defendants' reliance on *Clemons v. Crawford*, 585 F.3d 1119 (8th Cir. 2009). Setting aside the fact that *Clemons* involved a different protocol, a different nucleus of operative fact, and numerous different parties, the court was not presented with and did not decide any claim that the former protocol violated Section 217.420. *Clemons* offers no guidance on the issue.

Defendants next argue that the Court must consider Missouri's "statutory scheme as a whole." Opposition at 7. Defendants do not explain what the statutory scheme "as a whole" is, and they make no effort to reconcile the prisoner-anesthesia statute with the method-of-execution statute, other than by urging the Court to ignore the former. But the two statutes are in fact easily reconciled: the Department of Corrections may carry out executions using "lethal injection" or "lethal gas," Mo. Rev. Stat. § 546.720.1; but, if the chosen method happens to involve a general anesthetic for the therapeutic and medical purpose of sedation, it must abide by a statute specifically addressing such anesthesia for prisoners. Mo. Rev. Stat. § 217.420.1.

Defendants seem to suggest that they may choose **any** method of "lethal injection" or "lethal gas," and need not obey the laws governing whatever substances they plan to administer. But nothing in the method-of-execution statute exempts the DOC or its execution team from any other requirement of law. The statute exempts medical personnel from state professional discipline for the general act of participating in an execution; but that is all. *See* Mo. Rev. Stat. § 546.720.4. If the legislature had intended to exempt executioners from all state law, it would have said so.

B. The Eighth Amendment and Missouri's execution statute require Defendants to establish and follow a binding protocol, rather than a document that is changeable by bureaucratic whim or affidavit.

Defendants' only real quibble is with the source of law that requires them to have a binding protocol. Opposition at 8-9. Quite aside from whether Due Process and the Ex Post Facto clause require a protocol, the Eighth Amendment requires it. In *Taylor v. Crawford*, 487 F.3d 1072 (8th Cir. 2007), and *Clemons v. Crawford*, 585 F.3d 1119 (8th Cir. 2009), the Eighth Circuit upheld Missouri's former protocol **only** after Judge Gaitan ordered Defendants' predecessors to produce a written protocol for before-the-fact judicial review, and after the D.O.C. terminated its dyslexic surgeon-executioner. This Court and the Eighth Circuit did not require a written protocol for judicial review only to allow Defendants to change it at the last minute in order to evade their review. Accordingly, this Court has already recognized that a protocol is constitutionally required. *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 962 (W.D. Mo. 2010) ("Where the **Eighth Amendment requires protocols** that include adequate safeguards against unnecessary pain, *see Taylor*, 487 F.3d at 1084, and superior courts have indicated that the involvement of medical professionals and rules for administration enhances such safeguards, the safeguards provided by the CSA and FDCA are not irrelevant.") (emphasis added).

Missouri's execution statute also requires a protocol. It provides, "The section of an execution protocol that directly relates to the administration of lethal gas or lethal chemicals is an open record, the remainder of any execution protocol of the department of corrections is a closed record." Mo. Rev. Stat. § 546.720.2. The statute presumes that Defendants will establish a protocol and that the protocol will explain how to administer the lethal chemicals and to how take all "directly related" actions.

Defendants' latest execution method fails this requirement. Defendants point to midazolam as a means of preventing pain, but this drug is not part of the written protocol; Defendants leave its timing and purpose undefined, and its dosage "is being left to M3." Opposition at 13.

On the separate question of due process and the Ex Post Facto Clause, Defendants misread the Eighth Circuit's opinion in *Williams v. Hobbs*, 658 F.3d 842 (8th Cir. 2011). The court in *Williams* rejected the prisoners' claims only because the attorney general pledged to timely notify the prisoners' attorneys of the execution protocol. *Id.* at 850. *Williams* supports Plaintiffs' claims here, in light of the Missouri executioners' claimed discretion to "amend" the protocol by affidavit or otherwise. *See id.* ("The prisoners' contention that a FOIA request will be ineffective because the Director may change the protocol too close to the date of execution to allow them time to make such a request is more troublesome.").

Considering this Court's orders in *Taylor* and *Ringo*, Missouri's execution statute, and the Eighth Circuit's reasoning in *Williams*, it does not aid Defendants to cite the Fifth Circuit's ruling in *Sepulvado v. Jindal*, No. 13-70007, 2013 WL 4711679 (5th Cir. Aug. 30, 2013). It is true that *Sepulvado* reversed the district court's stay in *Hoffman v. Jindal*, No. 12-796-JJB, 2013 WL 489809 (M.D. La. Feb. 7, 2013), which Plaintiffs cited in their motion twelve days before *Sepulvado* was issued. But the Court in *Sepulvado* carefully limited its holding to due process claims, as opposed to Eighth Amendment claims. *Id.* at *2-*3 (noting that district court did not resolve Eighth Amendment claim, and distinguishing Eleventh Circuit authority "because the court grounded its decision in the Eighth Amendment and the Equal Protection Clause"). Plaintiffs do not need a due process claim to show that Defendants must establish

and follow a known protocol.

C. The new protocol includes a medical procedure and is therefore subject to the same law that governs other medical procedures.

Defendants make much of their "board-certified anesthesiologist" and his plan to administer "clinical" doses of propofol and midazolam, yet they insist that an execution is not a medical procedure. Opposition at 10. They agree that the initial dose of propofol and lidocaine serves the ostensible therapeutic purpose of preventing pain, and they argue that midazolam serves this same purpose. In seeking to treat the known risk of severe propofol-evoked pain, Defendants are acting as medical professionals, hold themselves out as medical professionals, and must accept scrutiny as medical professionals.

The Court recognized as much when it refused to dismiss the *Ringo* case. It rejected Defendants' arguments that federal drug safety statutes should not apply to executions in which "[s]afety, measured as the lack of adverse effects on a person, is not at issue." *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 962 (W.D. Mo. 2010). Medical personnel help to protect the condemned from unconstitutional pain, the Court explained, and the federal statutes provide safeguards for the sound medical administration of drugs by ensuring that they are safe and effective for their intended use. *Id.* at 961-62. So it is here: medical malpractice law ensures that physicians and nurses act "with the degree of skill and learning ordinarily used by members of the defendant's profession." *Devitre v. Orthopedic Center of St. Louis*, 349 S.W.3d 327, 335 (Mo. 2011). M3's proposed conduct violates the accepted practice of medicine, and it thereby places Plaintiffs at risk of pain and suffering over and above the statutory purpose of an execution.

D. The Supremacy Clause and the doctrine of *Ex parte Young* afford Plaintiffs a private right of action on their claims concerning the FDCA and the CSA.

This Court rejected Defendants' point about the absence of a private right of action (Opposition at 10-11) in its Order denying, in pertinent part, the *Ringo* defendants' motion for judgment on the pleadings. *Ringo v. Lombardi,* No. 09-4095-CV-C-NKL, 2010 WL 3310240, at *4-*5 (W.D. Mo. Aug. 19, 2010). Motions for judgment on the pleadings must stand or fall by the same standard as motions to dismiss, which is the same standard that governs the futility or non-futility of a proposed amendment. *Wescott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990); *In re Senior Cottages of America*, 482 F.3d 997, 1001 (8th Cir. 2007). This Court properly allowed the *Ringo* plaintiffs to go forward on their Supremacy Clause claim even though the Court had held that the statute did not provide a private right of action. Although the Court later opined on summary judgment that it was not certain about the preemption theory (*Ringo* Doc. No. 263 at 19), it repeatedly held that the claim made enough sense for the *Ringo* plaintiffs to be allowed to continue the case, including to conduct discovery.

Defendants next argue that Plaintiffs lack standing, but they distort Plaintiffs' claims: "Plaintiffs' argument is essentially that the Department of Corrections violates the CSA and FDCA by using chemicals to **reduce the risk of discomfort** to inmates from an execution." Opposition at 12 (emphasis added). To the contrary, Plaintiffs claim that the initial dose of propofol will **cause** excruciating pain, just as Drs. Heath and Dershwitz swear that it will. Defendants have chosen to cause that pain by making Missouri the only jurisdiction to use propofol in executions.

E. Defense counsel's bare assertions about midazolam illustrate the need for further discovery.

Defendants fail to specify anything about their plan to administer midazolam, other than to say that M3 will decide its dosage. Opposition at 13. We still do not know when the drug will be administered, by whom, through what means, in what amount, or the level of sedation that Defendants seek to accomplish. Without the slightest evidentiary support, counsel suggests that the midazolam might produce unconsciousness "at the moment of death" (as in *Baze v. Rees*, 553 U.S. 35 (2008)), that its purpose is to "reduce the risk of pain," and that the prisoner cannot possibly suffer a lingering death because the drug is meant to "lower the risk of discomfort." *Id.* at 13-14. But all we know from the Defendants about midazolam is what Mr. Dormire's affidavit says: the prisoner will receive a "clinical dose" of midazolam or a "similar sedative" at some unspecified point before he is injected with propofol and lidocaine. Ex. 5 ¶ 6. The fact that this information comes from Mr. Dormire, who has no medical training, rather than from the doctor who will presumably oversee the midazolam, is particularly troubling. Discovery will reveal precisely what Defendants intend to do, as well as when, how, and why they intend to do it; defense counsel's naked assertions and those of Mr. Dormire are no substitute.

Neither does it help Defendants to claim the benevolent intention of reducing pain. Opposition at 13-14. Defendants' subjective motivations for adopting the new protocol cannot be known without discovery. But more importantly, an Eighth Amendment claim does not require proof that Defendants are intentionally inflicting pain. Only two justices took that view in *Baze*. *See* 553 U.S. at 94 (Thomas, J., concurring, and joined by Scalia, J.).

CONCLUSION

The Defendants' protocol has become, in this Court's words, a moving target. Plaintiffs cannot, in less than a month, prepare for a trial on facts materially different from those that existed before August 2, 2013. The existing pleadings and previous discovery are not adequate for Plaintiffs to properly present to the Court the issues raised by the late-introduced changes in execution procedure. The motion to amend the scheduling order should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 9th day of September, 2013, to Michael J. Spillane and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

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